IN THE HIGH COURT OF JUDICATURE AT BOMBAY
O.O.C.J.
NOTICE OF MOTION NO.158 OF 2006
IN
WRIT PETITION NO.2731 OF 2005

Vascular Concepts Private Limited .. Petitioner
v/s.
The Commissioner,
Food & Drug Administration, Mumbai
and others .. Respondents

Mr.T.N.Subramanian with Mr.M.S.Karnik and Ms.B.V.Tendulkar i/by Mr.M.S.Karnik for the petitioner.

Mr.Amjad Sayyed, Assistant Government Pleader for the respondent Nos.1 and 2.

Ms.N.V.Masurkar for the respondent No.3.

CORAM : R.M. LODHA &
J.P.DEVADHAR, JJ.

DATED : 3RD MAY, 2006.

P.C.

On 22nd December, 2005, rule was issued in the matter. However, the interim relief was rejected.

2. On 6th October, 2005, Ministry of Health and Family Welfare (Department of Health), Government of India issued notification that reads thus-

"MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health)

New Delhi, the 6th October, 2005

S.O.1468(E).- In pursuance of the sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following sterile devices intended for external or internal use in human beings as drugs with immediate effect, namely:-

(i) .....

(ii) Drug Eluting Stents

(iii) .....

(iv) .....

(v) .....

(vi) .....

(vii) .....

(viii) .....

(ix) .....

(x) .....”

[F.No.11014/2/2005-DMS & PFA]
RITA TEAOTIA, Jt.Secy.

3. On 7.10.2005, it was notified by GSR 627(E) that control over manufacture of these devices would be exercised by Drugs Controller General of India under the Drug Control Rules.

4. The Ministry of Health and Family Welfare, Government of India thereafter issued guidelines to be effective from 1st March,

2006 which interalia reads thus-

> "For the purpose of import of Devices specified above, the procedure for registration and import licence as prescribed under the Drugs and Cosmetics Rules shall be followed.
>
> 1. A period of 60 days would be provided for the importers to make application for import and registration from the date of publication of these guidelines.
>
> 2. In case of devices which have not been imported in the country before the date of notification no import would be permitted without the approval of the competent authority.
>
> 3. For the time being and for a period upto six months, until an application is approved or rejected, whichever is earlier, the devices which are currently in use will be permitted to be sold. In case of stents or drugs eluting stents the import will not be permitted if the applicant has sold less than One thousand stents of the particular specification prior to the date of issue of these guidelines.
>
> 4. Separate committees consisting of subject experts and representative of DCG(I) office would be set up for their expert advice for evaluation of specific categories of devices. The expert committees would formulate their own benchmarks and procedures for evaluations and the standards to which such devices should conform.
>
> REGISTRATION OF MEDICAL DEVICES FOR IMPORT
>
> ....."

5. Based on the aforesaid guidelines effective from 1st March, 2006, this notice of motion has been taken out by the petitioner for interim relief.

6. From the gazette notification dated 6.10.2005, it is clear that the Drug Eluting Stents which is sterile device is considered as `drug' under section 3(b)(iv) of the Drugs and Cosmetics Act, 1940. Subsequent GSR dated 1.10.2005 clarifies that the control over manufacture of these devices would be exercised by the Drug Controller of India. The guidelines effective from 1st March, 2006 provide that for the time being and for a period upto 6 months, until an application is approved or rejected, whichever is earlier, the devices which are currently in use may be permitted to be sold. In case of stents or drug eluting stents the import will not be permitted if the applicant has sold less than one thousand stents of the particular specification prior to the date of issue of the said guidelines. Keeping in view the notification dated 6.10.2005, GSR dated 7.10.2005 and the guidelines effective from 1st March, 2006, if the petitioner gets appropriate permission for sale of Drug Eluting Stents from Drugs Controller General of India upon satisfying the said authority that it has sold one thousand stents of the particular specification prior to the date of issue of the guidelines effective from 1st March, 2006, the impugned order dated 6th June, 2005 passed by the Commissioner, Food and Drug

Administration, Mumbai should not come in the way of the petitioner for sale of Drug Eluting Stents as may be permitted by the Drugs Controller General of India.

7. We, accordingly, dispose of the notice of motion by the following order:

> In the event of the petitioner getting permission from the Drugs Controller General of India for sale of Drugs Eluting Stents upon satisfying the said authority that it has sold not less than one thousand stents of particular specification prior to the guidelines issued effective from 1st March, 2006, the operation of the impugned order shall remain stayed so long as such permission of Drugs Controller General of India remains operative.

(R.M.LODHA, J.)

(J.P.DEVADHAR, J.)